



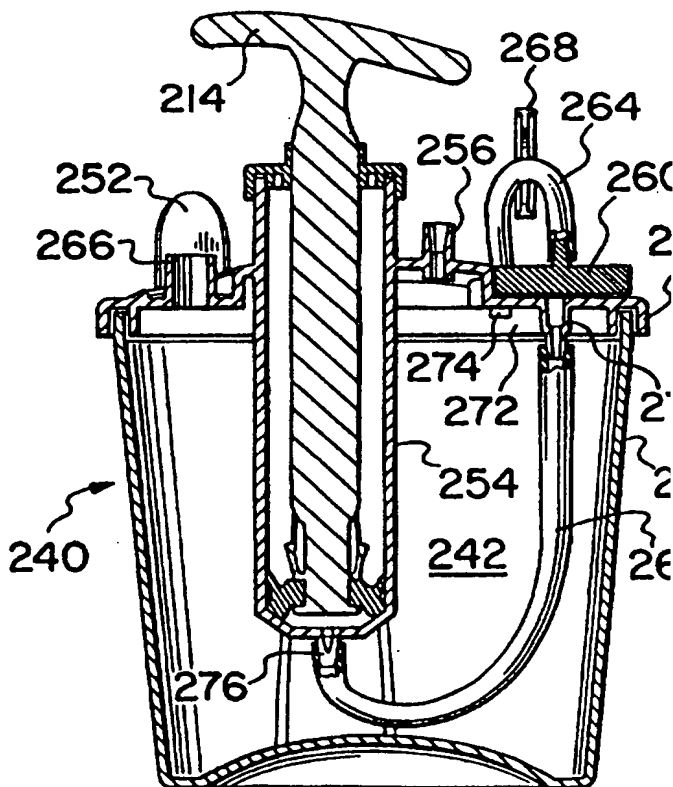
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY

(51) International Patent Classification ⁶ : A61L	A2	(11) International Publication Number: WO 9
		(43) International Publication Date: 23 October 1997
<p>(21) International Application Number: PCT/CA97/00256</p> <p>(22) International Filing Date: 11 April 1997 (11.04.97)</p> <p>(30) Priority Data: 08/631,435 12 April 1996 (12.04.96) US</p> <p>(71)(72) Applicant and Inventor: REITSMA, Bert, J. [NL/CA]; 5735 Knights Drive, Manotick, Ontario K4M 1B2 (CA).</p> <p>(74) Agent: WOOD, Max, R.; Scott & Aylen, Suite 1000, 60 Queen Street, Ottawa, Ontario K1P 5Y7 (CA).</p>		<p>(81) Designated States: AL, AT, AU, BB, BG, BR, BY, CN, CZ, EE, GE, HU, IL, IS, JP, KP, KR, LK, L, MG, MK, MN, MX, NO, NZ, PL, PT, RU, SG, S, TT, UA, UZ, VN, ARIPO patent (GH, KE, LS, SZ, UG), Eurasian patent (AM, AZ, BY, KG, K2, TJ, TM), European patent (AT, BE, CH, DE, I, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), O (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, N, TG).</p> <p>Published <i>Without international search report and to be upon receipt of that report.</i></p>

(54) Title: APPARATUS FOR DRAINING SURGICAL WOUNDS

(57) Abstract

Apparatus for draining surgical wounds is disclosed. The apparatus consists of a container which includes a vacuum chamber and a fluid collection chamber. A manual vacuum pump is in fluid communication with the vacuum chamber but isolated from the fluid collection chamber by a hydrophobic and bacteriostatic filter to prevent contamination of the pump with collected fluid and ejection of hazardous airborne contaminants into the atmosphere. The advantages include an inexpensive, versatile, easy to operate wound drainage system which eliminates the requirement for sterilization and the handling of wound drainage wastes, and a convenient manual vacuum pump which may be operated to evacuate the container to any desired subatmospheric pressure, which can be maintained or adjusted during postoperative use so that an optimum postoperative wound drainage regimen can be followed.



APPARATUS FOR DRAINING SURGICAL WOUNDS

TECHNICAL FIELD

5 The present invention relates to surgical wound drainage and, in particular, to apparatus for post operatively draining and collecting fluids from a closed surgical wound.

BACKGROUND OF THE INVENTION

10 It has long been recognized that large surgical wounds are advantageously drained of fluids to facilitate healing and improve the readaptation of tissue layers surrounding the wound. Considerable effort has therefore been invested in designing devices to provide consistent and effective drainage of surgical wounds by partially evacuated collection containers which promote surgical wound drainage.

15 Such devices may be generally divided into three categories, compressible containers, electric vacuum machines and precharged disposable containers. All three categories of wound drainage devices operate on the principle that a partial vacuum provides suction in the surgical wound to promote the drainage of fluids from the wound. The first category includes simple mechanical devices which are spring
20 biased collapsible containers or containers with elastic memory. Both are generally made of resilient elastomeric material. Such containers are manually compressed to provide suction for removing and collecting fluids from surgical wounds. One example of this type of device is disclosed in United States Patent 3,993,080 to Loseff which issued November 23, 1976. Such devices suffer from certain drawbacks. First, such devices have a limited capacity for providing suction, the
25 amount of suction provided being related to the elasticity and the volume of the container. Second, they generally provide no means for monitoring the subatmospheric pressure in the container. It is therefore difficult to judge how much suction is being applied to a wound, and the quality of the vacuum may deteriorate as the container loses its elastic memory over time. Third, such containers collect
30 the fluid drained from the wound and must therefore be discarded after use or emptied, cleaned and sterilized, with all the attendant hazards and time consuming activity involved in handling medical waste.

The second category of wound drainage devices includes the vacuum machines equipped with electrically powered vacuum pumps which are generally controlled by electronic circuits that poll sensors to monitor vacuum levels. Examples of such devices are disclosed in United States Patent 4,569,674 to Phillips et al. which issued February 11, 1986, and United States Patent 3,836,287 to Grosholz et al. which issued September 17, 1974. These are complex, expensive machines which may also be used as wound irrigation devices. Some of these machines accumulate fluid in disposable containers (see U.S.P. 3,836,287) to minimize maintenance. The disadvantages of such machines are that they are generally bulky, most are unusable by ambulatory patients, and they are expensive to manufacture and maintain.

The third category of such devices includes lightweight molded plastic or glass containers which are pre-evacuated to provide either a "high" (about .9 bar) or a "low" (about .4 bar) vacuum. For example, see United States Patent 4,642,093 to Härle which issued February 10, 1987. These containers are transportable and are usually disposable. Some also include a gauge to indicate whether there is negative pressure in the container. Some of the disadvantages of these devices are that they are useless once the vacuum has been discharged from the container, do not provide adjustable vacuum, and do not provide consistent vacuum over an extended period of time. They also do not permit an optimal regimen for surgical wound drainage whereby the suction force is regulated over time to optimize the readaptation of tissue surrounding the wound. Furthermore, these containers must be carefully handled to ensure that the vacuum is not released before or during use because they provide no mechanism for recharging the vacuum once it is discharged.

An exception to these categories is represented by United States Patent No. 5, 279,550 to Habib et al. which issued on January 18, 1994. This patent describes an autotransfusion system with an integrated manual vacuum pump. While this system has advantages over the prior art in a limited application of autotransfusion after orthopaedic surgery where bone marrow is opened, it suffers from several drawbacks with respect to wound drainage. First, the pump is positioned under the reservoir on a side of the unit making it difficult and awkward to use. Second, the unit is regulated to maintain only a maximum of 100 mm/Hg of vacuum so that it cannot be used for an optimum wound drainage regimen. Third, air exhausted by the

vacuum pump is not filtered, so airborne viruses or other hazardous aerosols which escape from blood in the collection chamber may be ejected into the atmosphere. Fourth, there is no vacuum chamber provided so vacuum is difficult to regulate. Fifth, the unit is not suitable for use by ambulatory patients. And, the unit is
5 expensive to manufacture and cannot be reused.

In about 90% of surgical procedures significant blood loss is rare and wound drainage fluids are generally not transfusable because they contain breakdown products of the wound repair process. Surgical wounds requiring drainage may be located in either "soft tissue", such as found in the abdominal cavity, or in "hard
10 tissue", such as ligaments, etc. It has long been recognized that these two types of tissue require different treatment regimens to ensure that the tissues surrounding the surgical wound are optimally readapted and healing is facilitated. Soft tissues should not be subjected to high vacuums for prolonged periods of time, i.e. suction forces in excess of about .5 bar, while hard tissue can be subjected to higher vacuum for
15 effective drainage. Hence, precharged wound drainage containers are offered in low pressure and high pressure units, as described above.

It has also been discovered that optimal post-operative results are generally achieved if a regimen is followed in which the suction force for surgical wound drainage is varied over time. The amount of suction for optimal results depends on
20 the type of tissue in which the wound is located, as well as the time that has elapsed since the wound was created. It is therefore desirable to provide an apparatus for draining surgical wounds which permits the subatmospheric pressure for promoting drainage to be monitored and adjusted in accordance with an optimal regimen.

It is also known that the suction force provided by most apparatus for draining surgical wounds decreases proportionally with the volume of fluid collected. In other
25 words, as fluid is drained from a wound, the suction force applied by the container is proportionally reduced. It is therefore desirable to provide a container in which the vacuum can be adjusted to an optimal level until the container has collected its nominal capacity of fluid, or the container is no longer needed.

The spread of blood-borne diseases such as AIDS, Hepatitis-C and tuberculosis
30 have also heightened awareness of the dangers of handling wound drainage fluids. It has therefore been recognized that such fluids must be safely contained at all times

and that aerosols should not be permitted to escape from a wound drainage collection container.

There therefore exists a need for a simple, easy to use, inexpensive wound drainage system that overcomes these known disadvantages of the prior art, and is adapted to permit one to follow an optimal post-operative wound drainage regimen.

SUMMARY OF THE INVENTION

It is an object of the invention to provide a simple surgical wound drainage apparatus for removing and collecting fluids from a closed wound which is inexpensive to manufacture.

It is another object of the invention to provide a simple surgical wound drainage apparatus which provides an inexpensive, safe, disposable collection container for wound drainage wastes.

It is a further object of the invention to provide a simple surgical wound drainage apparatus which provides adjustable and rechargeable vacuum using a hand-operated vacuum pump that is easy to operate and convenient to use.

It is another object of the invention to provide an inexpensive surgical wound drainage apparatus which permits the suction force to be regulated over time to facilitate an optimal regimen of surgical wound drainage.

A surgical wound drainage apparatus from removing and collecting fluids from a closed wound comprising a rigid container which includes a sealed fluid collection chamber having an inlet for connection with a wound drainage line and a hand operated vacuum pump for evacuating the fluid collection chamber characterized in that:

the rigid container includes a vacuum chamber and a fluid collection chamber, the fluid collection chamber being in fluid communication with the vacuum chamber; the manual vacuum pump is mounted to a top of the container and in fluid communication with the vacuum chamber; and

a filter positioned between the vacuum pump and the fluid collection chamber so that all fluid communicated between the fluid collection chamber and the vacuum pump passes through the filter, the filter being effective to prevent a flow of liquids

to the pump and to remove microorganisms from the air withdrawn from the fluid collection chamber by the pump.

In accordance with the invention, there is provided a two-chambered container for draining surgical wounds. A first chamber serves as a drainage fluid collection chamber while the second chamber serves as a vacuum chamber to which a hand operated vacuum pump is connected. The hand operated vacuum pump and the vacuum chamber are interconnected by a fluid communication path which includes a hydrophobic and bacteriostatic filter to prevent wound drainage fluids from entering the pump and to inhibit contamination of the atmosphere with airborne infectious agents. The container is also preferably provided with a bellows gauge for indicating the subatmospheric pressure in the collection chamber. The vacuum chamber is preferably provided with a vacuum release valve which permits a user to regulate the pressure in the collection chamber. The advantages of this apparatus are two-fold. First, the apparatus permits an optimal suction force to be maintained in the surgical wound, and even if the collection chamber is substantially full to its nominal capacity. Second, the apparatus permits an optimal regimen for wound drainage to be followed, wherein the suction force is maintained at an optimal level that varies over time.

A further embodiment of the invention provides a two-chambered container which is closed by a removable cover. This container also includes a vacuum chamber and a drainage fluid collection chamber. The drainage fluid collection chamber, however, is adapted to receive a blood bag for collecting the fluid drained from the surgical wound. This permits all or part of the collected fluid to be reinfused in the patient should circumstances warrant.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be explained by way of example only and with reference to the following drawings, wherein:

FIG. 1a shows a side elevational view of a configuration for a container in accordance with the invention wherein the container is oval in plan view and include two chambers, a vacuum chamber and a fluid collection chamber for collecting wound drainage fluids;

FIG. 1b shows a side elevational view of the container shown in FIG. 1a, illustrating how the container may be manufactured in three sizes having a nominal capacity of 350, 500 or 900 ml;

FIG. 1c shows a cross-sectional view of the container shown in FIG. 1a, illustrating the construction and the interconnection of the two chambers of the container;

FIG. 2a shows another configuration for a preferred embodiment of the container for a surgical wound drainage apparatus in accordance with the invention wherein the container is reusable and includes two chambers, a first chamber for housing the manual pump and a second chamber for housing a blood bag which receives and contains wound drainage fluid so that the fluid may be disposed of or used for transfusion back to the patient when appropriate;

FIG. 2b shows a side elevational view of the container shown in FIG. 2a;

FIG. 3a shows a perspective view of another configuration for the container in accordance with the invention wherein a barrel of the vacuum pump extends into the fluid collection chamber but the pump is isolated from direct fluid communication from the fluid collection chamber;

FIG. 3b shows a cross-sectional view of the container shown in FIG. 3a;

FIG. 4 shows a cross-sectional view of a disposable vacuum pump designed especially for the containers in accordance with the invention;

FIG. 5 is a graphical representation showing the relationship between the average number of pump strokes and the vacuum in inches and millimeters Hg;

FIG. 6 shows a graphical representation of the vacuum in inches and millimeters Hg in relation to volume provided by certain wound drainage containers known in the prior art as well as containers in accordance with the invention; and

FIG. 7 shows a graphical representation of an optimal regimen for draining surgical wounds in both hard and soft tissues.

BEST MODE OF CARRYING OUT THE INVENTION

FIGS. 1a-c illustrate a first configuration of a preferred embodiment for a surgical wound drainage container in accordance with the invention. The container, generally indicated by the reference 100, includes a wound drainage fluid collection

chamber 102 and a vacuum chamber 104. This embodiment provides several distinct advantages over the known prior art. First, wound drainage fluid is isolated from the vacuum chamber so the vacuum pump is never contaminated regardless of the volume of fluid collected in the wound drainage fluid collection chamber 102.

5 Second, it is well known that in most commonly used wound drainage systems, the subatmospheric pressure decreases proportionally to the volume of collected fluid. This problem is minimized by using a vacuum chamber 104 isolated from the wound drainage fluid collection chamber 102. Third, a manual vacuum pump is positioned on top of the container (see FIG. 1c) so that it is easy to use and the container is
10 stable when the pump is in use. Fourth, as will be explained below, the manual vacuum pump is isolated from the fluid collection chamber by a filter adapted to prevent the flow of liquids or microorganisms from the fluid collection chamber to the pump. Thus, contaminated air is not ejected from the container when the pump is operated to induce a vacuum in the fluid collection chamber.

15 The container 100 shown in FIG. 1a is preferably blow molded from a synthetic resin in a manner well known in the art. The sidewall of the container 100 is reinforced by smooth ribs 106 to provide strength under vacuum. The ribs 106 also provide an ergonomic grip to facilitate handling the container 100. An end of the wound drainage fluid collection chamber 102 also preferably includes a smooth area
20 108 in the form of a rectangular window which may be used to adhere a label or may be used for a marker to indicate, for example, the amount of fluid drained from a surgical wound on a daily basis.

FIG. 1b shows a schematic diagram of how various size wound drainage containers in accordance with this embodiment are constructed. The container is
25 preferably manufactured in 350 ml, 500 ml and 900 ml sizes. In blow molding, the same tool is used for molding the top of all three sizes of the container. A single tool is used for molding a bottom of each container as well. To produce a 500 ml and a 900 ml container, additional inserts are provided to add the sections 500 (for 500 ml) and 900 (for 900 ml), as appropriate. Containers having different volumes
30 can be manufactured using the same principles.

FIG. 1c shows a cross-sectional view of the container 100 in accordance with the invention. As explained above, the container 100 includes a wound drainage

fluid collection chamber 102 and a vacuum chamber 104. The two chambers are interconnected by a compression molded web 110 formed during the blow molding process in a manner well known in the art. The compression molded web 110 preferably includes a hole 112 useful for suspending the container 100 when appropriate. A bottom of the container 100 preferably includes a compression molded rib 114 to reinforce the bottom against collapse when the container 100 is evacuated. This container, as in all containers in accordance with the invention, should withstand a vacuum of about .9 atmospheres without collapse.

The wound drainage fluid collection chamber 102 is provided with three integral cylindrical orifices molded in a top wall 116 of the container. A first orifice 118 supports a collapsible bellows 120 made of a resilient plastics material. The bellows 120 preferably includes a coil spring 122 which is tempered to support the bellows 120 in a manner that the bellows 120 provides an accurate measure of the subatmospheric pressure in the wound drainage fluid collection chamber 102.

Surrounding the orifice 118 and the bellows 120 is a pressure gauge 124 which is embossed or printed with an indicia (not illustrated) for indicating the subatmospheric pressure in the fluid collection chamber 102. The pressure gauge 124 in combination with the bellows 120 will preferably accurately indicate a subatmospheric pressure of from about .1 to at least about .5 atmospheres. A second orifice 126 is provided with a Luer Lock® connector 127 to which a wound drainage tube may be connected. The Luer Lock® connector 127 is preferably spun welded into a top of the orifice 126 after the molding process is complete. A third orifice 128 provides a connection for a vacuum tubing 130 which in turn is connected to the vacuum chamber 104. A vacuum tubing connector 131 is also preferably spun welded to a top of the vacuum tubing orifice 128 after blow molding is complete. The vacuum chamber 104 includes two orifices in its top wall 132. A T-connector 136 is spun welded to a vacuum orifice 134. The T-connector 136 provides a first connection for the vacuum tubing 130 and a second connector for a vacuum release valve 138, which is preferably a duck bill valve that permits the vacuum to be manually released and/or adjusted. The vacuum tubing 130 is preferably interrupted by a filter 140. The filter 140 is preferably a hydrophobic filter which inhibits the passage of fluids from the fluid collection chamber 102 to the vacuum chamber 104. If the fluid collection

chamber 102 overfills during a period when the vacuum system is unattended, the hydrophobic filter 140 prevents fluid from overflowing into the vacuum chamber 104. The filter 140 is also preferably bacteriostatic to prevent the migration of bacteria from fluid in the fluid collection chamber 102 to the vacuum chamber 104.

5 The second orifice 142 is adapted for the connection of a vacuum pump barrel 144. It therefore preferably includes an external thread (not illustrated) which is integrally molded therewith for threadably engaging the vacuum pump barrel 144 to the vacuum chamber 104.

10 When a wound drainage tubing is connected to the Luer Lock® connector 127 and the vacuum pump is operated to induce a subatmospheric pressure in the vacuum chamber 104, air is withdrawn from the fluid collection chamber 102 and the induced vacuum causes the bellows 120 to compress, indicating the subatmospheric pressure induced. Fluid from the wound is then drawn through the wound drainage tubing (not illustrated) and the Luer Lock® connector 127 into the fluid collection chamber 15 102. The pump may be operated intermittently to maintain the subatmospheric pressure in the fluid collection chamber 102 at a preferred level in accordance with a regimen selected by the attending physician. Because the vacuum chamber 104 is isolated from the fluid collection chamber 102, an optimal subatmospheric pressure can be maintained in the fluid collection chamber 102 regardless of the volume of 20 fluid collected. In most prior art wound drainage systems, the subatmospheric pressure declines proportionally with the amount of fluid collected in the fluid collection chamber. The prior art systems therefore frequently fail to provide optimal wound drainage throughout the post-operative period. As will be explained below in more detail with reference to FIG. 7, it has been discovered that an optimal regimen 25 for wound drainage requires adjustment over time of the suction pressure applied to the wound.

FIG. 2a is a perspective view of another configuration for a wound drainage container 200 in accordance with the invention. The container 200, unlike the container described above, is intended to be reused. Wound drainage fluid is 30 collected in a collapsible receptacle such as a blood bag 202 which is enclosed in a fluid collection chamber 204 that is segregated from a vacuum chamber 206 by a partition 208 that is integrally molded with a sidewall 210 of the container 200. Th

partition 208 includes an orifice (not illustrated) for establishing fluid communication between the vacuum chamber 206 and the fluid collection chamber 204. The orifice is preferably located near a top of the container 200 in order to prevent the migration of collected fluids from the fluid collection chamber 204 to the vacuum chamber 206 in the event that the blood bag 202 ruptures or otherwise discharges fluid. The container 200 includes a removable top cover 212 which preferably snaps on and off the sidewall 210 using a plastic interference joint in a manner known in the art. The top cover 212 is provided with an O-ring (not illustrated), or the like, to provide a fluid impervious seal in a manner well known in the art so that the container 200 can be evacuated to a subatmospheric pressure of at least .5 atmospheres. Mounted to the top cover 212 is a vacuum pump 214 of the type described above. Also mounted to the top cover 212 is a bellows gauge 216 of the type described in relation to FIG. 1c above. The bellows gauge 216 is constructed and functions in an identical manner with the bellows gauge described with reference to FIG. 1c. A bottom end of the bellows gauge 216 is in fluid communication with the fluid collection chamber 204. A wound drainage tube connector 218 is connected to and extends through the top cover 212. A lower end of the wound drainage tube connector 218 provides a connection for the blood bag 202. A top end of the wound drainage tube connector 218 includes a Luer Lock® connector 220 for the attachment of a wound drainage tube (not illustrated). The wound drainage tube connector 218 optionally includes a control valve 222 which may be operated to control fluid flow through the wound drainage tube connector 218. The sidewall 210 of the container 200 preferably includes an integrally molded or printed volume scale 224 to indicate the volume of liquid collected as well as a smooth rectangular write strip 226 which may be used to record the daily discharge collected in the container 200. The top cover 212 may also include a hinged hanger handle 228, or a similar attachment useful for suspending the container 200 when required.

FIG. 2b shows a side elevational view of the container 200. In use, the top cover 212 is removed from the container 200 and a fluid collection receptacle such as a blood bag 202 is connected to a bottom end of the wound drainage tube connector 218. The cover 212 is then replaced taking care that the blood bag 202 is suspended in the container 200 and not pinched or trapped between the container

sidewall 210 and the container cover 212. The vacuum pump 214 is then operated to induce the desired subatmospheric pressure in the fluid collection chamber 204 as indicated by the bellows gauge 216 or by the number of pump strokes (see FIG. 5). If a control valve 222 is not provided on the wound drainage tube connector 218, the wound drainage tube is connected to the wound drainage tube connector 218 before the vacuum pump 214 is operated. After the wound drainage tube has been connected to the wound drainage tube connector 218, the vacuum is adjusted if necessary by operating the vacuum pump 214 until the required subatmospheric pressure is established. When the blood bag 202 is full, or wound drainage is complete, the control valve 222 is closed, the wound drainage tube is disconnected from the drainage tube connector 218, the cover 212 is removed from the container 200, the blood bag 202 is sealed with a clamp and disconnected from the wound drainage tube connector 218. The collected fluid may then be disposed of or, when appropriate, used for transfusion back to the patient after an appropriate treatment process, if necessary.

FIG. 3a shows a perspective view of a further configuration for a wound drainage container 240 in accordance with the invention. The container 240, unlike the container 200 described above, is intended to be completely disposable. The assembled container 240 includes a drainage fluid collection chamber 242 (see FIG. 3b) defined by a sidewall 244 of the container 240. The sidewall 244 includes opposed vertical recessed areas 246 to facilitate gripping the container 240 when it is handled. A cover 248 is permanently bonded to the container sidewall 244 when the container 240 is assembled. The cover 248 includes integrally molded parts for supporting a bellows gauge 250, a bellows gauge guard 252, a pump barrel 254, a drainage tube connector 256, a pressure release valve 258, a hydrophobic filter 260 and a vacuum tubing orifice 262 which is adapted to accommodate a vacuum tubing 264, the arrangement of which will be explained in detail with relation to FIG. 3b. The pump barrel 254 supports a vacuum pump 214 the construction of which is described with reference to FIG. 4.

FIG. 3b shows a cross-sectional view of the container 240 shown in FIG. 3a. As explained above, the sidewall 244 of the container 240 defines a fluid collection chamber 242 which is preferably constructed to hold 300, 500 or 900 ml. The

sidewall 244 is capped by the cover 248 which is molded to define the integral pump barrel 254 which accommodates the manual vacuum pump 214. Also integrally molded into the cover 248 are a filter connector 270 for connecting the hydrophobic filter 260, and a bellows gauge connector 266. The pump barrel 254 extends into the fluid collection chamber 242 when the cover 248 is mounted to the sidewall 244.

The vacuum pump 214 is isolated from direct fluid communication with the fluid collection chamber 242 by the pliable vacuum tubing 264 which connects to a bottom end of the filter connector 270 that extends through a vacuum chamber 272 located above the fluid collection chamber 242 and integrally molded into the cover 248. On the opposite side of the hydrophobic filter 260 is another section of vacuum tubing 264 which connects the filter 260 to a vacuum port 274 that extends through the cover 248 into the vacuum chamber 272. A sliding clamp 268 is preferably provided on the exposed section of the vacuum tubing 264 to permit the vacuum tubing 264 to be closed when the container 240 is not being evacuated using the vacuum pump 214. The sliding lock 268 prevents the intrusion of drainage fluid through the vacuum chamber 272 and the vacuum tubing 264 into the hydrophobic filter 260 should the container 240 be accidentally overturned for an extended period of time. As will be understood by those skilled in the art, the vacuum chamber 272 is provided with at least one path of fluid communication with the fluid collection chamber 242. That path in the form of a slot or one or more holes (not illustrated) is preferably sized to permit the ready passage of air but to inhibit the passage of wound drainage fluid from the fluid collection chamber 242 to the vacuum chamber 272. When the vacuum pump 214 is operated, air is drawn from the fluid collection chamber 242 through the vacuum chamber 272 and the vacuum tubing 264 and expelled to atmosphere around the pump handle. The bottom length of the vacuum tubing 264 is connected to a tubing connector 276 and the filter connector 270 before the cover 248 is applied to the sidewall 244 of the container 240. The cover 248 is preferably attached to the sidewall 244 using an adhesive effective with the plastic material of which the disposable container 240 is constructed.

To use the container 240, it is placed on a flat surface and the sliding clamp 268 is released to permit the container 240 to be evacuated and a wound drainage tubing is attached to the wound drainage tubing connector 256, which may, for example, be

a Luer Lock® connector. The manual vacuum pump 214 is then operated the number of strokes required to evacuate the container 240 to the desired target subatmospheric pressure. The bellows gauge 250 (see FIG. 3a) provides at least a qualitative gauge of the subatmospheric pressure in the container 240. The bellows gauge guard 252
5 may be graduated with an index to provide a quantitative measure of the subatmospheric pressure in the container 240. As described above, the container 240 is designed to be disposable. If it becomes full before wound drainage is complete, it may be emptied into a suitable receptacle by releasing any residual vacuum using the pressure release valve 258 and disconnecting the wound drainage tubing from the
10 drainage tube connector 256. A drainage tube connected to a suitable receptacle is then connected to the drainage tube connector 256, the sliding clamp 268 is moved to the locked position to close the vacuum tubing 264 to ensure that fluid does not flow into the hydrophobic filter 260 and the container 240 is inverted to drain fluid from the container 240. To facilitate drainage, the vacuum release valve 258 may be
15 opened slightly to permit air to enter the container 240 as fluid is displaced.

FIG. 4 shows a cross-sectional view of the stroke of the pump 214, which was designed expressly for use with disposable containers in accordance with the invention. Manual vacuum pumps such as disclosed in United States Patent 4,889,250 are generally considered too expensive to be disposed of with containers.
20 A pump having a novel piston 278 made of a resilient material such as neoprene rubber is configured with an upwardly directed, flared skirt 280 which is shaped to closely conform to the inner surface of the pump barrel 254. When the pump is stroked upwardly, the flared skirt 280 forms a seal with the barrel 254 and draws air upwardly through the vacuum tubing connector 276 past an umbrella valve 282.
25 When the pump reaches a top of its stroke shown in ghost lines at the top of the figure, the umbrella valve 282 closes the orifice in the tubing connector 276 and as the pump piston 278 is returned to the bottom of the barrel 254, the skirt 280 collapses inwardly and the air is expelled from the pump barrel 254. This novel manual vacuum pump permits the commercial production at reasonable cost of a
30 wound drainage container that is completely disposable.

FIG. 5 shows a graphic representation of the vacuum in inches and millimeters of mercury induced in the containers in accordance with the invention in relation to

the number of strokes that the vacuum pump is operated. On average, a subatmospheric pressure of about 550 mm Hg is induced with about 45 pump strokes depending on the size and model of the container to which the pump is attached. As is apparent, very little effort is required to maintain a desired vacuum when using a wound drainage system in accordance with the invention.

FIG. 6 shows a graphic representation of the subatmospheric pressure in inches Hg and millimeters Hg in relation to the volume of fluid collected in a vacuum container. A line 300 is an approximation curve of the vacuum in a precharged, high vacuum container such as disclosed in United States Patent 4,642,093 to Härle. As is apparent, the subatmospheric pressure in the container is very high when the container is first connected to a wound drainage tubing, assuming that the connection is perfectly executed and that the vacuum is not lost during the process. The vacuum thereafter declines steadily as fluid is drained from the wound and is substantially zero when the nominal capacity of the container is reached. Line 310 represents the relationship between volume and the vacuum in a precharged low vacuum container such as one taught by Härle. In general, the vacuum in low vacuum precharged containers is more steady than in high vacuum containers because those containers generally are precharged to a high vacuum (about 800 mm Hg) but the vacuum is reduced to approximately 200 mm Hg by a pressure reduction valve in the wound drainage tube connector of the container. Line 320 represents the vacuum curve of a compressible container such as taught in United States Patent 3,993,080 to Loseff. As is apparent, such containers require frequent work and provide inconsistent vacuum. Line 330 is exemplary of a vacuum curve provided by a container in accordance with the invention. The shape of the curve will depend on the frequency with which the vacuum is recharged using the manual pump but in general, any level of vacuum including the high vacuum of up to about 800 mm Hg can be achieved and maintained until the nominal capacity of fluid is collected in the container. Unlike the prior art portable systems wherein vacuum universally decreases to near zero as the nominal capacity of the container is approached, the container in accordance with the invention provides up to a maximum vacuum until such time as nominal capacity is reached and the wound drainage tubing is disconnected from the container.

FIG. 7 shows a graphic representation of two optimal wound drainage regimens which can be practiced using a wound drainage system in accordance with the invention. The horizontal axis of the graph shows time in days while the vertical axis of the graph shows vacuum in inches and millimeters Hg. Line 340 represents an optimal wound drainage regimen for a surgical wound located in hard tissue such as striated muscle. In accordance with the optimal regimen, the wound drainage container is evacuated to a subatmospheric pressure of about 500 mm Hg as soon as the wound drainage tube is implanted and the container is connected. A high pressure is maintained in the container for the first post-operative day. After the first day, the vacuum is adjusted to about 300 mm Hg. That pressure is gradually decreased over the next three days until the pressure has reached about 250 mm Hg. Normally, wound drainage is ceased at about the fourth post-operative day. Prior to removing the drain from the surgical wound, the cavity is preferably evacuated to at least 500 mm Hg to avoid any residual fluid leaks around the fistula following the drain removal. After a few minutes at high vacuum, the vacuum is released and the drain is removed from the surgical wound.

Line 350 represents the optimal regimen for draining a surgical wound located in the soft tissue. During the first day, a very low vacuum of about 25 mm Hg is maintained to enhance the soft tissue repair process. At the end of the first post-operative day, the vacuum is gradually increased until the vacuum reaches about 200 mm Hg and that vacuum is maintained with a slight gradual decrease until about three and a half days when the pressure is increased to a maximum of about 500 mm Hg for a brief period of time before the drain is removed to avoid residual fluid leak via the fistula, as described above. Other regimens may also be found to be particularly effective for a given surgical wound. Any normal regimen can readily be followed, however, if a wound drainage container in accordance with the invention is used during post operative treatment.

INDUSTRIAL APPLICABILITY

The wound drainage system in accordance with the invention provides lightweight, reliable wound drainage units that may be used by ambulatory patients. The built-in manual vacuum pump and segregated vacuum chamber permits a desired

vacuum level to be maintained by any attendant, including the patient, regardless of the volume of collected fluid, until a nominal capacity of fluid is collected.

5 The wound drainage system in accordance with the invention also permits the practice of an optimal regimen based on the type of tissue in which the surgical wound is located. Because of the degree of control which can be achieved using the wound drainage systems in accordance with the invention, it is not only possible but practical to adhere closely to an optimal regimen, thus facilitating the readaptation of damaged tissue and the healing process.

10 These wound drainage systems are inexpensive to manufacture and simple to assemble. They are adapted to be used interchangeably for draining both hard and soft tissue wounds, so that only one type of unit need be stocked by hospitals to serve all wound drainage needs. This simplifies purchase ordering, inventory control and equipment distribution.

15 The invention therefore provides a cost-effective solution that alleviates many of the shortcomings of similar prior art devices.

Changes and modifications to the embodiments described may be made by those skilled in the art without departing the spirit of the invention, which is intended to be limited solely by the scope of the appended claims.

We Claim:

1. A surgical wound drainage apparatus for removing and collecting fluids from a closed wound comprising a rigid container which includes a sealed fluid collection chamber having an inlet for connection with a wound drainage line and a hand operated vacuum pump for evacuating the fluid collection chamber

characterized in that:

the rigid container includes a vacuum chamber and a fluid collection chamber, the fluid collection chamber being in fluid communication with the vacuum chamber

the manual vacuum pump is mounted to a top of the container and in fluid communication with the vacuum chamber; and

a filter positioned between the vacuum pump and the fluid collection chamber such that all fluid communicated between the fluid collection chamber and the vacuum pump passes through the filter, the filter being effective to prevent a flow of liquids to the pump and to remove microorganisms from the air withdrawn from the fluid collection chamber by the pump.

2. A surgical wound drainage apparatus for removing and collecting fluids from a closed wound as claimed in claim 1 wherein a barrel of the manual vacuum pump extends into the fluid collection chamber, and a tubing interconnects a bottom end of the barrel with the vacuum chamber so that the pump is in fluid communication with the vacuum chamber but there is no direct fluid communication between the pump and the fluid collection chamber.

3. A surgical wound drainage apparatus for removing and collecting fluids from a closed wound as claimed in claim 2 wherein a portion of the tubing between the hydrophobic filter and the vacuum chamber is exposed on an outside of the container and is provided with a clamp for sealing the tubing during periods when the pump is not being operated to evacuate the container to ensure that collected fluid does not migrate to the filter if the container is accidentally inverted during such periods.

4. A surgical wound drainage apparatus for removing and collecting fluids from a closed wound as claimed in claim 1 wherein the manual vacuum pump is disposed within the vacuum chamber.
- 5 5. A surgical wound drainage apparatus for removing and collecting fluids from a closed wound as claimed in claim 3 wherein the vacuum chamber is located above the fluid collection chamber in a cover of the container.
- 10 6. A surgical wound drainage apparatus for removing and collecting fluids from a closed wound as claimed in claim 1 wherein the container includes a removable cover and the fluid collection chamber is adapted to accommodate a fluid collection bag adapted to connect in fluid tight relationship with the connector so that fluid drained from the closed wound is collected directly in the fluid collection bag.
- 15 7. A surgical wound drainage apparatus for removing and collecting fluids from a closed wound as claimed in any preceding claim wherein the container further includes a pressure gauge in fluid communication with a one of the vacuum chamber and the fluid collection chamber.
- 20 8. A surgical wound drainage apparatus for removing and collecting fluids from a closed wound as claimed in claim 17 wherein the pressure gauge is a bellows gauge.

1/6

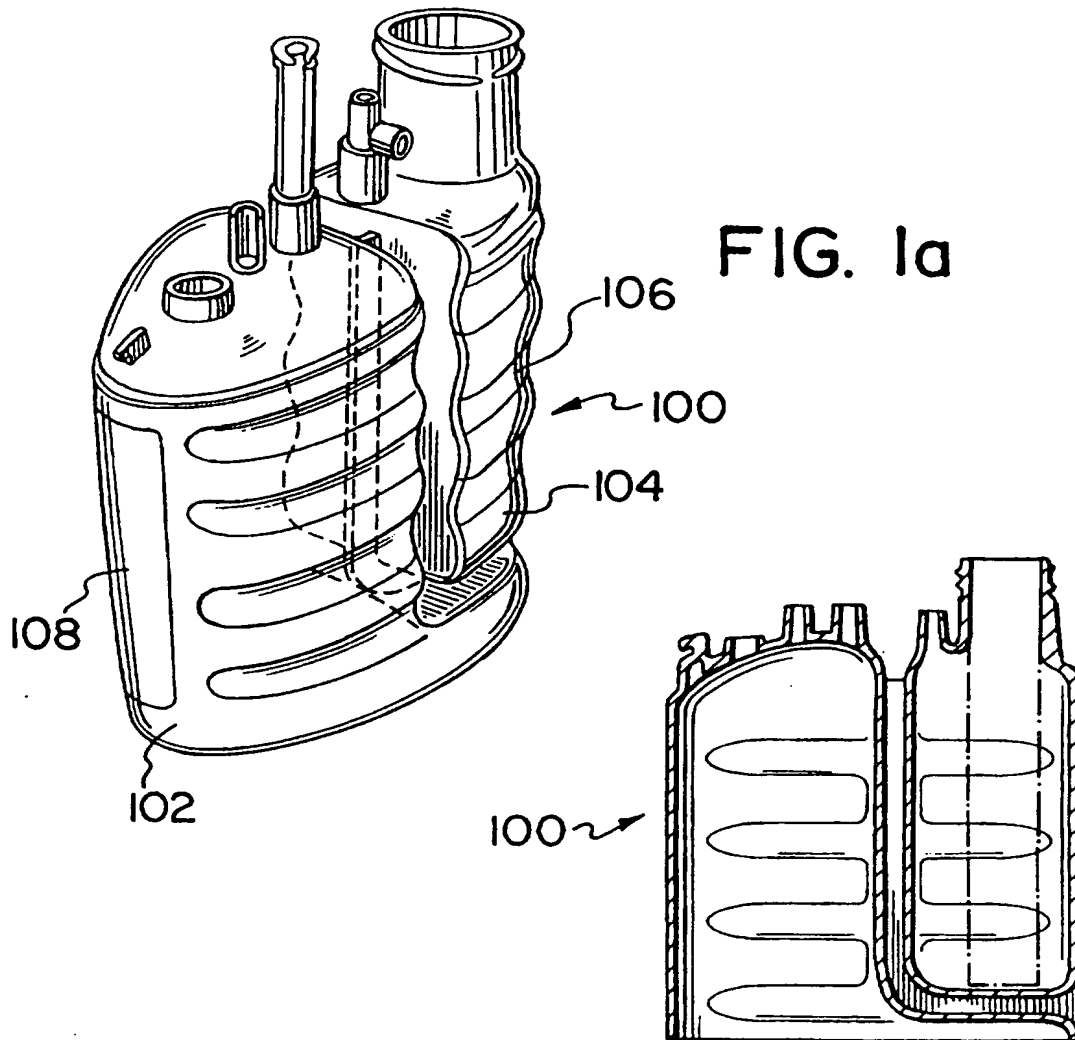
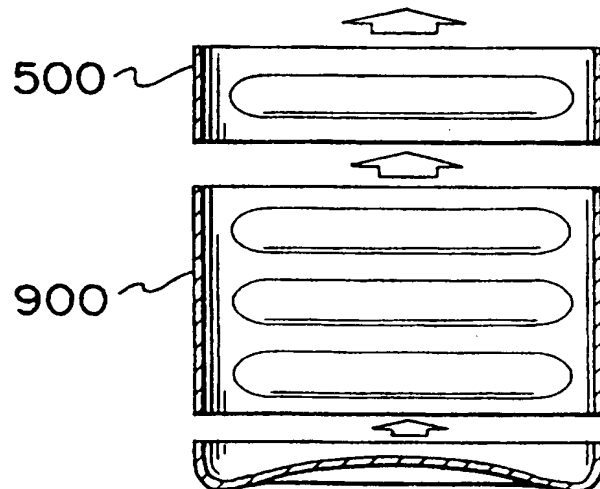
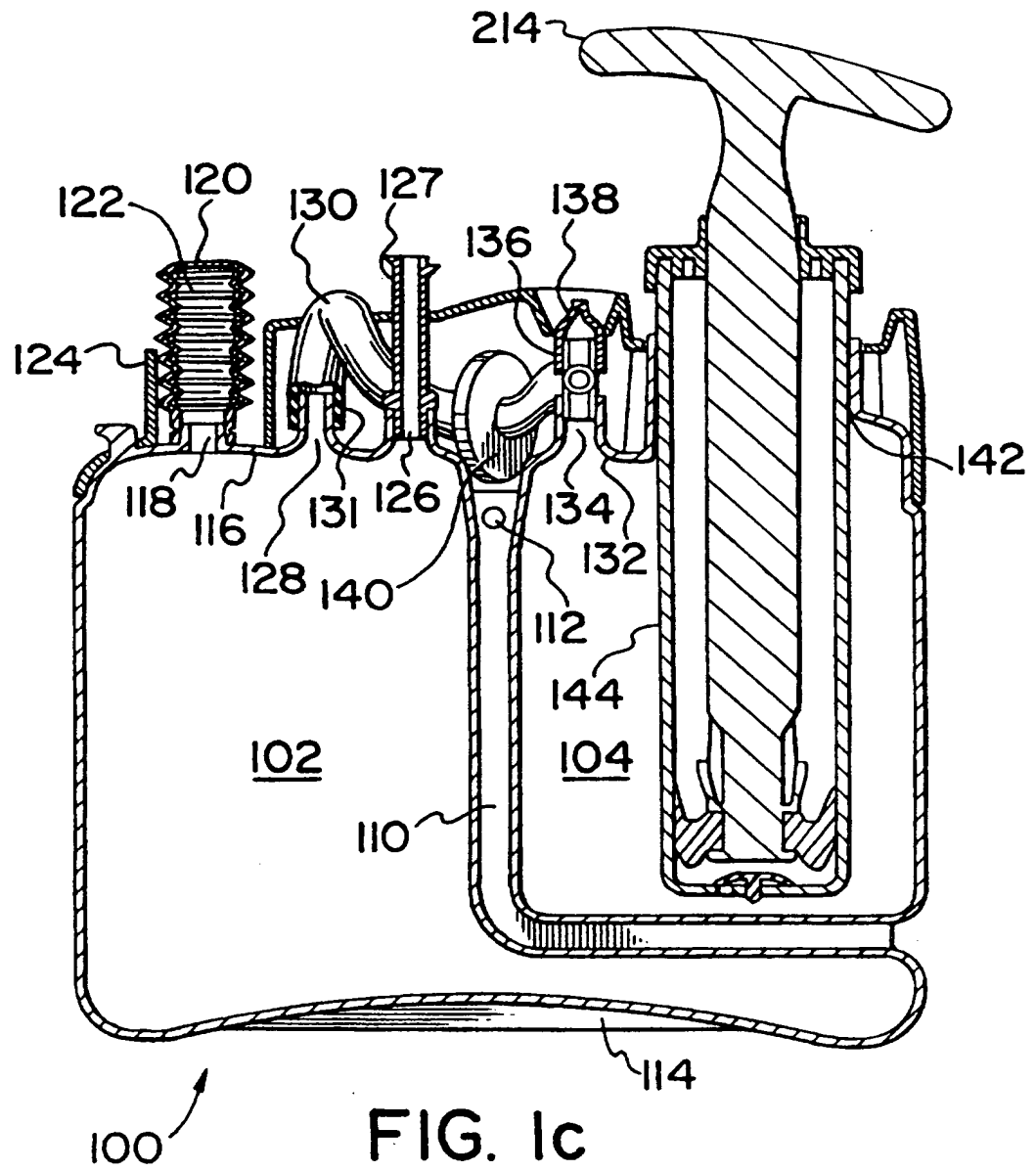


FIG. 1b



2/6



3/6

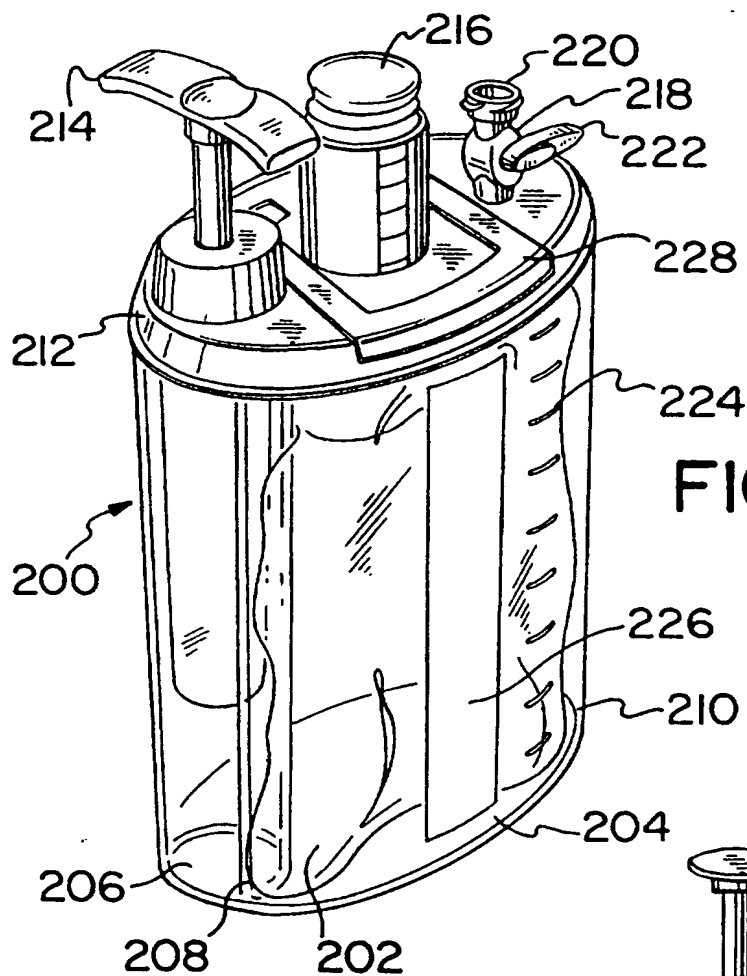
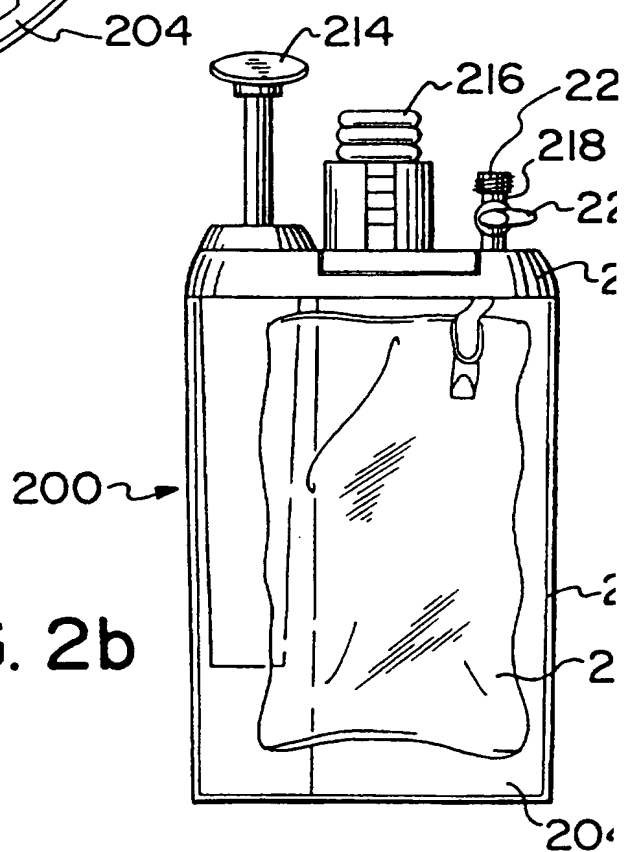


FIG. 2b



4/6

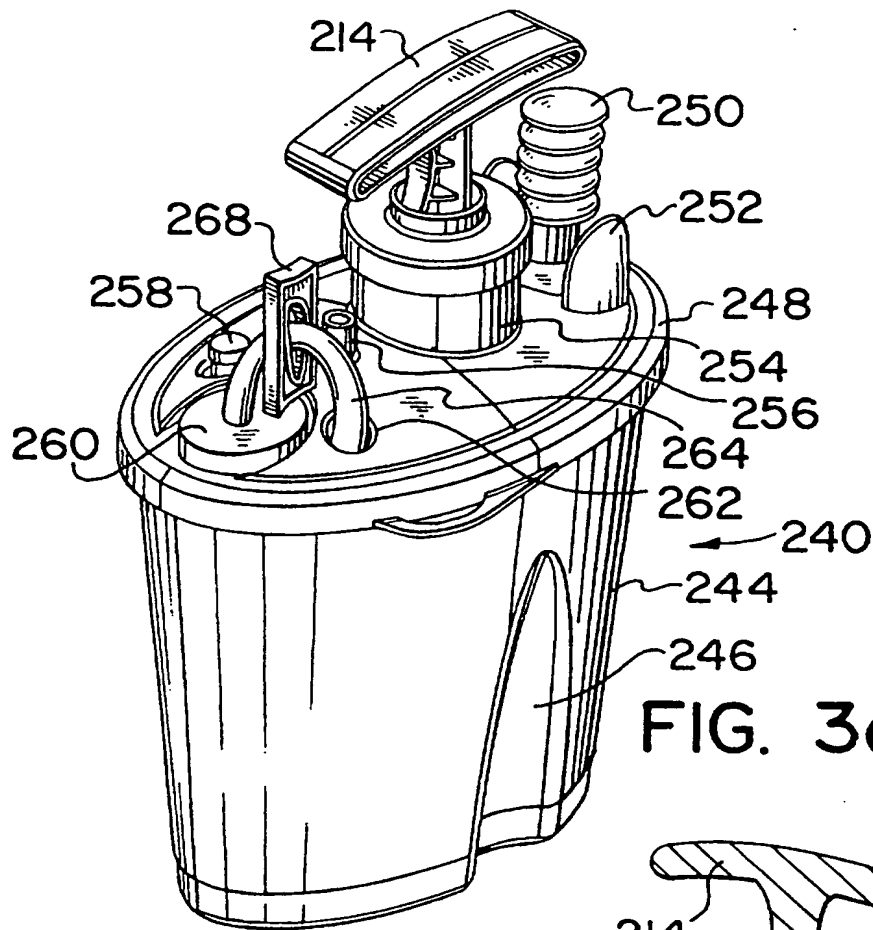


FIG. 3a

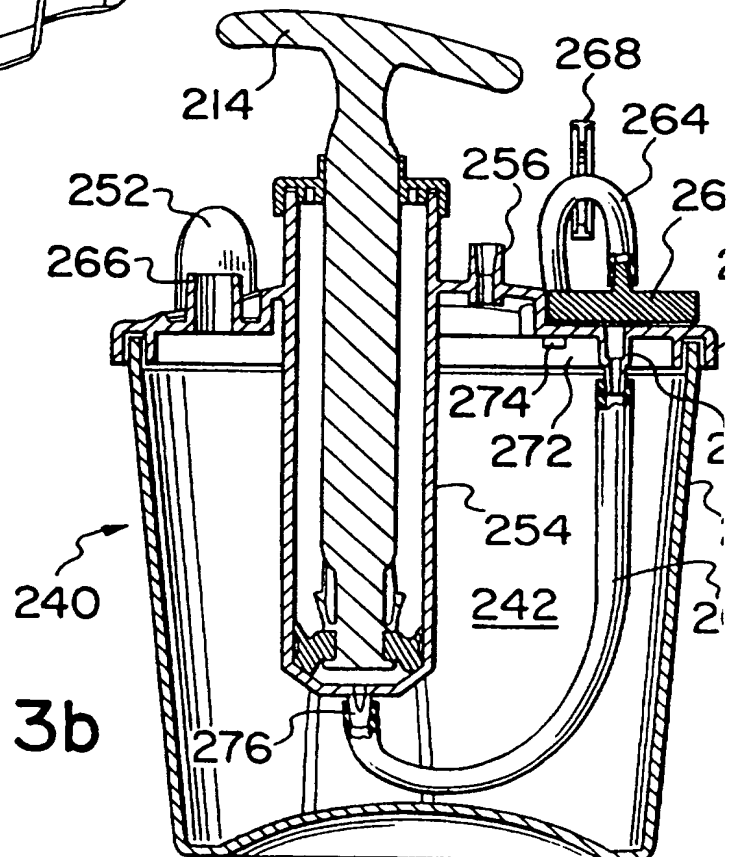


FIG. 3b

5/6

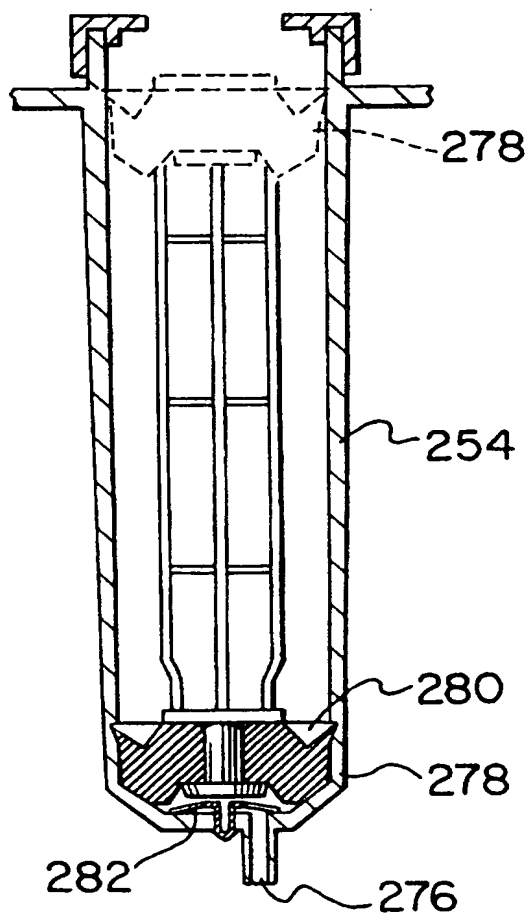


FIG. 4

6/6

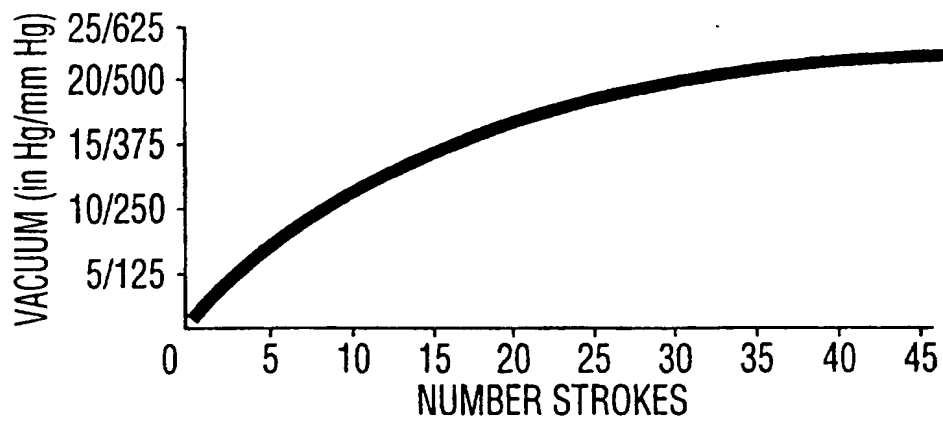


FIG. 5

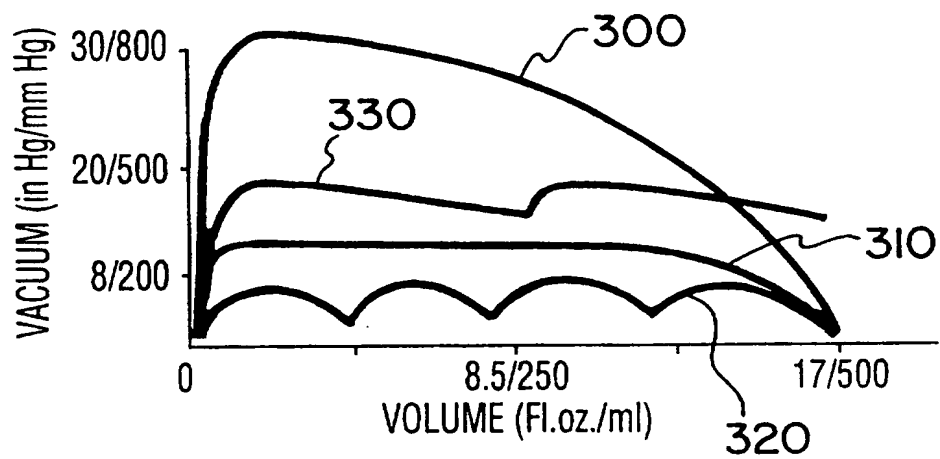


FIG. 6

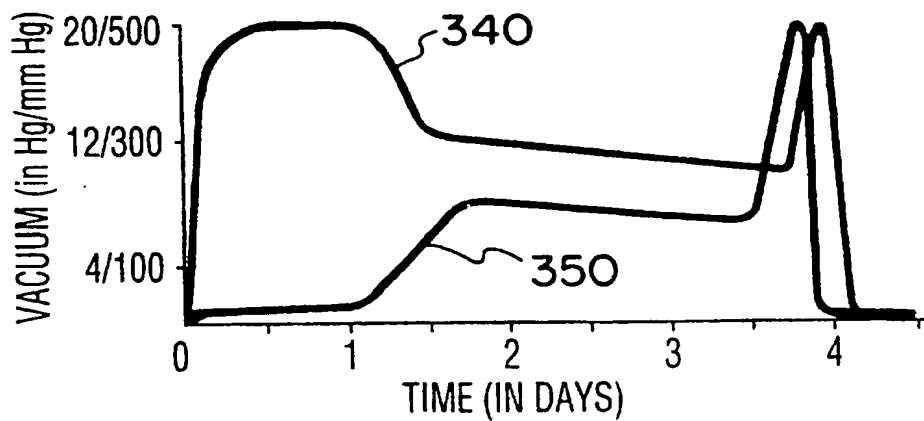


FIG. 7

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☐ **BLACK BORDERS**

☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**

☒ **FADED TEXT OR DRAWING**

☒ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**

☐ **SKEWED/SLANTED IMAGES**

☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**

☐ **GRAY SCALE DOCUMENTS**

☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**

☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**

☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.